Supreme Court, U.S.
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No. 97-226

In The

Supreme Court of the United States

October Term, 1996

GARY E. ACKLES,

Petitioner,

v.

RICHARD F. LUTTRELL AND PLETCHER FLYING SERVICE, INC., A CORPORATION, N/K/A D&L FLYING SERVICE, INC., A CORPORATION; BRADY COEN; AIR CARE, INC., A FOREIGN CORPORATION AND ELF ATOCHEM NORTH AMERICA, INC., A FOREIGN CORPORATION,

Respondents.

On Petition For A Writ Of Certiorari To The Supreme Court For The State Of Nebraska

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the Nebraska Supreme Court correctly held that the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") preempts state common law claims that challenge the adequacy of a manufacturer's EPA-approved pesticide label.

RULE 29.6 STATEMENT

Pursuant to Rule 29.6, respondent Elf Atochem North America, Inc. states that it has the following parent companies and nonwholly owned subsidiaries or affiliates:

Elf Aquitaine
Elf Aquitaine, Inc.
Elf Atochem S.A.
Reserveco Inc.
Anning Decco Fine Chemical Company, Ltd.
Metco North America, Inc.
Derivados Metalorganicos "DEMOSA"
Elf Atochem Colombia
Elf Atochem Italia
Elf Atochem North Europe
Nitto Kasei Company Ltd.
Safepack Products Ltd.
Safepack Services Ltd.
Elf Atochem Japan Ltd.
Atochem Yoshitomi Ltd.
Elf Atochem Agri S.A.
Elf Atochem Brasil S.A.
Elf Atochem Verwaltungs
Japan Thiochemical Co.
Desarrollo Quimico Indus.
Quimica Pennwalt SA de CV
Pennwalt, S.A. de C.V.
Elf Atochem North Europe
Industrias Clorotec
Petroquimica PWT SA de CV
Cloro de Tehuantepec
Servicios Corporativos
Union Minera del Sur
Pennwalt, S.A. de C.V.
Elf Atochem Colombia
Turco Nederland B.V.
Turco Products Limited

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BRIEF FOR THE RESPONDENT IN OPPOSITION

As a threshold matter, the Nebraska Supreme Court decision from which Petitioner Gary E. Ackles ("Petitioner") seeks review is not final. The Nebraska court remanded this case to the state district court to permit Petitioner to amend his negligence claim. He has done so, and those claims remain unlitigated. This matter therefore is not final and is not ripe for this Court's consideration.

Even if further review by this Court were procedurally proper, Petitioner offers no sound substantive ground for this Court to hear the case. Notably absent from the Petition is any hint of confusion in the lower courts. Indeed, as the Nebraska Supreme Court recognized, "every federal court of appeals that has addressed the issue before us has, in the wake of the *Cipollone* decision, held that both failure-to-warn and labeling-based claims brought under common-law causes of action against manufacturers of pesticides are preempted" by the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.* (Appendix to Petition at 1a, p. 7). Given this uniform interpretation of FIFRA, Respondent Elf Atochem North America, Inc. ("Elf Atochem") respectfully submits that there is simply no reason for this Court to grant the writ and hear this case. Indeed, Petitioner does not even attempt to distinguish this case from *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992), in which this Court held that a preemption clause virtually identical to FIFRA's expressly preempted state common law labeling claims. Despite the Nebraska Supreme Court's repeated reliance on *Cipollone* in its

decision, Petitioner's "Reasons for Granting the Writ" does not even mention the case.

REASONS FOR DENYING THE PETITION

I. THE DECISION BELOW IS NOT FINAL AND THIS CASE IS CONTINUING IN THE NEBRASKA STATE COURT.

This Court should decline to hear this case because the proceedings below are not complete, and review of the case at this point in the litigation would generate piecemeal federal review of state court decisions. The Nebraska Supreme Court's decision does not meet this Court's requirements for finality because the decision does not dispose of Petitioner's action in its entirety. Indeed, Petitioner is even now litigating in state court in Nebraska some of the very issues that Petitioner seeks to present to this Court.

A brief procedural history may be helpful. At the time Elf Atochem brought its motion for summary judgment, Petitioner's complaint asserted theories of negligence and strict liability against Elf Atochem. Elf Atochem moved for summary judgment on both theories, and the district court granted the motion, finding that FIFRA preempted both causes of action. Petitioner appealed.

The Nebraska Supreme Court affirmed the district court's grant of summary judgment on Petitioner's strict liability claim based on FIFRA preemption. On the negligence claim, the court reversed the grant of summary

judgment and remanded the case to the district court to give Petitioner an opportunity to clarify his negligence claim by amendment. The court noted, however, that FIFRA would preempt any allegation based on negligent labeling. (Petition, Appendix at 1a).

On remand, Petitioner filed with the state district court his Seventh Amended Petition, which amended his negligence claim and asserted a brand new breach of implied warranty cause of action. (Appendix at App. 3-4, *infra*). Elf Atochem believes FIFRA also preempts the claims Petitioner asserts in his Seventh Amended Petition, and expects to litigate that issue in the Nebraska courts. Thus, not even the FIFRA issues in this case are final, much less the action as a whole.

This Court's review of state court decisions is limited to "[f]inal judgments or decrees rendered by the highest court of a State in which a decision could be had." 28 U.S.C. § 1257. This Court has held that, except in unusual circumstances not present here,[1] a state court judgment is not "final" for purposes of § 1257 if the state's highest court has remanded the case for further proceedings, unless that remand is for ministerial purposes only. *See Minnick v. California Dep't of Corrections*, 452 U.S. 105, 120-27 (1981); *Flynt v. Ohio*, 451 U.S. 619, 621-22 (1981), *see also Collins v. Miller*, 252 U.S. 364, 370 (1920) (an appealable judgment "should be final not only as to all the parties, but as to the whole subject-matter and as to all the causes of action involved"). Moreover, this Court has

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[1] *See, e.g., Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469, 479-85 (1975).

repeatedly held that a decision lacks finality where a state's highest court has remanded with directions that the parties may amend their pleadings. *See Missouri & Kansas R. Co. v. Olathe*, 222 U.S. 185 (1911); *Clark v. Kansas City*, 172 U.S. 334 (1899); *Meagher v. Minnesota Thresher Mfg. Co.*, 145 U.S. 608 (1892); *McComb v. County Commissioners*, 91 U.S. 1 (1876).

The remand here is anything but ministerial. The Nebraska Supreme Court remanded Petitioner's action to give him an entirely fresh start on his negligence claim by permitting him to amend his petition to state new allegations, and he has in fact done so. The future of Petitioner's new claims is uncertain; Elf Atochem may be entitled to summary judgment on Petitioner's new claims based on FIFRA preemption or some other ground, or the Nebraska courts may determine that Petitioner is entitled to a trial on the merits on the new claims. Only after the Nebraska courts resolve the new claims asserted in Petitioner's Seventh Amended Petition would a petition for certiorari in this Court be procedurally appropriate.

In sum, the petition before this Court seeks review of a decision that is not final, and this Court should deny review on that ground.

II. THERE IS NO CONFLICT IN THE LOWER COURTS.

Even if the Nebraska decision were final and further review by this Court were procedurally proper, review by this Court is unnecessary in light of the absence of any conflict in the lower federal courts or, for that matter, the

state appellate courts. Since this Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), all eight United States Courts of Appeals to consider the precise issue framed by Petitioner have concluded, like the Nebraska Supreme Court, that FIFRA expressly preempts state label-based claims. *Grenier v. Vermont Log Bldgs., Inc.*, 96 F.3d 559, 563 (1st Cir. 1996); *Welchert v. American Cyanamid, Inc.*, 59 F.3d 69, 71 (8th Cir. 1995); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 561 (9th Cir. 1995); *MacDonald v. Monsanto Co.*, 27 F.3d 1021 (5th Cir. 1994); *Worm v. American Cyanamid Co.* ["*Worm II*"], 5 F.3d 744, 749 (4th Cir. 1993); *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 371 (7th Cir. 1993); *Papas v. Upjohn Co.* ["*Papas II*"], 985 F.2d 516, 520 (11th Cir.), *cert. denied*, 510 U.S. 913 (1993); *Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.* ["*Arkansas-Platte II*"], 981 F.2d 1177, 1179 (10th Cir.), *cert. denied*, 510 U.S. 813 (1993). No federal appellate court has held to the contrary, and appellate courts in twenty states have reached the same conclusion.[2] Again, no state

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[2] In addition to the decision below, *see Barnes v. Sandoz Crop Protection Corp.*, 938 P.2d 95 (Ariz. App. Div. 1997), *review granted* (Ariz. June 24, 1997); *Buddington v. Sterling Winthrop, Inc.*, 1996 Conn. Super. LEXIS 2402 (Conn. Super. Ct. 1996); *Schuver v. E. I. DuPont de Nemours & Co.*, 546 N.W.2d 610 (Iowa), *cert. denied*, ___ U.S. ___, 117 S. Ct. 274, 136 L. Ed. 2d 197 (1996); *Lewis v. American Cyanamid Co.*, 682 A.2d 724 (N.J. Super. Ct. App. Div. 1996), *certif. granted* (N.J. July 11, 1997); *Babalola v. Chrystal Chems., Inc.*, 644 N.Y.S.2d 1 (N.Y. App. Div. 1996); *Eide v. E. I. DuPont de Nemours & Co.*, 542 N.W.2d 769 (S.D. 1996); *Hopkins v. American Cyanamid Co.*, 666 So.2d 615, 619 (La. 1996); *Quest Chem. Corp. v. Elam*, 898 S.W.2d 819, 820 (Tex. 1995); *Louisiana-Pacific Corp. v. Koppers Co.*, 32 Cal. App. 4th 599, 38 Cal. Rptr. 2d 257 (Cal. Ct. App. 1995); *Malone v. American Cyanamid Co.*, 649 N.E.2d 493 (Ill. Ct. App.), *appeal denied*, 657

appellate court decision stands for the opposite proposition. Moreover, despite Petitioner's argument that this Court's decision last term in *Medtronic, Inc. v. Lohr*, ___ U.S. ___, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996), compels a different result (Petition at 13-14), the unanimity among the courts deciding this issue has continued since *Medtronic*. *See* cases cited in Note 6 *infra*.

In sum, despite Petitioner's effort to create one, there is no "muddle" in the law, and no reason for this Court to hear this case.

III. THE NEBRASKA SUPREME COURT CORRECTLY HELD THAT FIFRA EXPRESSLY PREEMPTS PETITIONER'S COMMON LAW LABELING CLAIM.

Both the language of the FIFRA preemption clause and this Court's precedents fully justify the decisions of these eight federal and 20 state appellate courts upholding preemption. FIFRA's preemption clause is virtually

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N.E.2d 624 (Ill. 1995); *Hochberg v. Zoecon Corp.*, 657 N.E.2d 1263 (Mass. 1995); *Wadlington v. Miles, Inc.*, 922 S.W.2d 520 (Tenn. Ct. App. 1995), *appeal denied* (Tenn. Mar. 25, 1996); *Hue v. Farmboy Spray Co.*, 896 P.2d 682 (Wash. 1995); *Jenkins v. Amchem Prods., Inc.*, 886 P.2d 869 (Kan. 1994), *cert. denied*, ___ U.S. ___, 116 S. Ct. 80, 133 L. Ed. 2d 38 (1995); *Brennan v. Dow Chem. Co.*, 613 So.2d 131, 132 (Fla. 4th Dist. Ct. App. 1993); *ICI Americas, Inc. v. Banks*, 440 S.E.2d 38 (Ga. Ct. App. 1993), *aff'd in relevant part*, 450 S.E.2d 671 (Ga. 1994); *Moody v. Chevron Chem. Co.*, 505 N.W.2d 900, 903 (Mich. Ct. App. 1993), *appeal denied*, 525 N.W.2d 450 (Mich. 1994); *Hopkins v. Ciba-Geigy Corp.*, 432 S.E.2d 142, 146 (N.C. Ct. App. 1993); *Yowell v. Chevron Chem. Co.*, 836 S.W.2d 62, 66 (Mo. Ct. App. 1992); *Davidson v. Velsicol Chem. Corp.*, 834 P.2d 931, 937-938 (Nev. 1992), *cert. denied*, 507 U.S. 1051 (1993).

identical to the clause this Court addressed in *Cipollone*, where the Court held that the clause revealed Congress's clear intention to preempt label-based common law claims. This conclusion is confirmed by examination of this Court's earlier opinion in *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991) and its subsequent decision in *Medtronic, Inc. v. Lohr*, ___ U.S. ___, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996).

A. FIFRA GIVES EPA EXCLUSIVE AUTHORITY TO REGULATE PESTICIDE LABELING.

To allow the Environmental Protection Agency ("EPA") to carry out the goals of FIFRA, Congress vested in EPA the exclusive authority to regulate the content of pesticide labels.[3] In its exercise of this authority, EPA has established a comprehensive regulatory scheme to ensure the proper content of pesticide labels. Before a pesticide may be sold in the United States, it must be registered and its labeling approved by EPA. 7 U.S.C. § 136a(a). To secure registration, an applicant must submit proposed "labeling" for the product to EPA. 7 U.S.C. § 136a(c)(1)(C). "Labeling" includes not only the written or graphic matter attached to the container itself, but also all written, printed, or graphic matter accompanying the

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[3] When Congress passed FIFRA in 1947, it "was primarily a licensing and labeling statute." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). Although amendments added in 1972 broadened its scope, FIFRA maintained its sharpest focus on labeling. Indeed, "[t]he 1972 amendments significantly strengthened FIFRA's registration and labeling standards." *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 600 (1991).

container or to which reference is made on the attached label. 7 U.S.C. § 136(p).[4] EPA has promulgated detailed regulations specifying the scope, content, wording, and format of pesticide labeling. *See* 40 C.F.R. § 156.

Under FIFRA, it is unlawful for any person, including a manufacturer, to alter this approved labeling in any way without EPA's prior approval. *See* 7 U.S.C. § 136j(a)(2)(A). As a result, pesticide manufacturers are not free to add additional warnings on their own after a particular label has been approved. EPA's regulations require that any proposed labeling change requiring consideration of scientific data (such as additions or modifications of a warning or precaution) must be reviewed and approved by EPA in advance. *See* 40 C.F.R. § 152.81(b)(4). After reviewing the proposed labeling change and the supporting data, EPA may approve the labeling change as proposed, approve it on the condition that the manufacturer use different wording as specified by EPA, or reject it.

Applicants for pesticide registration must also submit the results of extensive scientific testing regarding the performance and the health and environmental safety of the pesticide formulation. 7 U.S.C. § 136a(c)(1)(D), (c)(2); 40 C.F.R. § 158.20. An applicant must conduct acceptable tests in accordance with the Pesticide Assessment Guidelines, guidelines that include, among other things, an

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[4] In addition, case law has interpreted the definition of label to include all explanatory brochures, advertising and promotional literature. *See, e.g., Select Pork, Inc. v. Babcock Swine, Inc.*, 640 F.2d 147 (8th Cir. 1981); *Larson v. Meckling Fertilizer Co.*, 243 N.W.2d 167 (S.D. 1976).

assessment of (1) product composition, (2) residue chemistry, (3) environmental effects, (4) potential hazards to humans, domestic animals and non-target organisms, (5) reentry protection, (6) pesticide spray drift evaluation and (7) product performance. 40 C.F.R. §§ 158.108 (chart and corresponding regulation sections), 158.202.

Finally, under FIFRA, EPA may not register a pesticide or approve its labeling unless the agency finds that the pesticide meets all of the following criteria:

> (a) its composition is such as to warrant the proposed claims for it;
>
> (b) its labeling and other material required to be submitted comply with the requirements of the Act;
>
> (c) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (d) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. § 136a(c)(5). In registering Penncap-M and approving its labeling, EPA necessarily concluded that Penncap-M, its testing, and the labeling accompanying it were reasonable and appropriate when the product was used in accordance "with widespread and commonly recognized practice." *Id.*

FIFRA and, through its authority, EPA, thus provide comprehensive and exclusive regulation of the labeling of pesticides in the United States.

B. FIFRA'S PREEMPTION CLAUSE EXPRESSLY PROHIBITS STATE-IMPOSED LABELING REQUIREMENTS.

Under the analysis this Court laid down in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992), such a comprehensive and exclusive federal regulation of pesticide labeling necessarily preempts any state-imposed labeling requirements on pesticides. The doctrine of federal preemption stems from the Supremacy Clause of the United States Constitution, which provides that the laws of the United States "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby." U.S. Const., art. VI, cl. 2. "[S]tate law that conflicts with federal law is 'without effect.' " *Cipollone*, 505 U.S. at 516 (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)). In *Medtronic, Inc. v. Lohr*, ___ U.S. ___, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996), this Court reaffirmed its long-held position that " ' "[t]he purpose of Congress is the ultimate touchstone' " of pre-emption analysis." 116 S. Ct. at 2250 (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)); *see also Cipollone*, 505 U.S. at 516.

As the appellate courts that have considered this issue have recognized, this Court's *Cipollone* decision is controlling of the preemption issue under FIFRA. In *Cipollone*, this Court interpreted the preemption clause in the Public Health Cigarette Smoking Act of 1969 ("PHCSA"), which read:

> (b) No *requirement* or prohibition based on smoking and health shall be imposed under State law with respect to the *advertising or promotion* of any cigarettes the packages of which

> are *labeled* in conformity with the provisions of this Act.

505 U.S. at 515 (quoting § 5(b) of PHCSA) (emphases added). The Court held that this language compelled preemption of state common-law labeling claims. *Cipollone*, 505 U.S. at 521-25.

Like the PHCSA, FIFRA clearly demonstrates that Congress intended to preempt state common-law claims premised on allegedly inadequate pesticide labeling. Indeed, when it passed FIFRA, Congress specified the precise extent to which the States may regulate pesticides. In § 136v of FIFRA, entitled "Authority of States," Congress allowed the states to regulate the sale or use of EPA-registered pesticides (§ 136v(a)), but expressly prohibited any state from establishing independent labeling or packaging requirements (§ 136v(b)):

> § 136v Authority of States
>
> (a) In general
>
> A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.
>
> (b) Uniformity
>
> Such State shall not impose or continue in effect any *requirements* for *labeling or packaging* in addition to or different from those required under this subchapter.

7 U.S.C. § 136v (emphasis added).

Comparison of the PHCSA and FIFRA clauses makes clear their substantive similarity. Both preemption clauses command the displacement of state "requirements" with respect to labeling that has been approved in accordance with the respective statutes. The lower appellate courts cited above have carefully compared these two preemption clauses and have uniformly concluded that they are substantively indistinguishable. As the United States Court of Appeals for the Seventh Circuit noted, "[n]ot even the most dedicated hair-splitter could distinguish" the preemption clause of FIFRA from that of the PHCSA. *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 371 (7th Cir. 1993).

The Petition before this Court utterly fails to account for the *Cipollone* decision and its impact on FIFRA preemption. Petitioner does not suggest that this Court should overrule *Cipollone*, the basic principles of which this Court reaffirmed just last term in *Medtronic*, nor does he propose any distinction between the preemption clauses of FIFRA and the PHCSA that would suggest a result different than in *Cipollone*. Instead, Petitioner ignores the *Cipollone* case entirely; indeed, the *Cipollone* citation does not even appear in Petitioner's Table of Authorities. Elf Atochem respectfully submits that Petitioner's failure even to mention *Cipollone* in its Reasons for Granting the Writ, notwithstanding the Nebraska Supreme Court's repeated citation of the case as controlling, severely undercuts Petitioner's suggestion that this case presents an issue justifying this Court's review.

The precedents of this Court to which Petitioner does cite do not sustain Petitioner's reading of them. Petitioner's citation to this Court's decision in *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991), is puzzling

because *Mortier* supports, rather than undermines, the Nebraska Supreme Court's conclusion. In *Mortier*, this Court held that FIFRA did not preempt a town ordinance regulating the use of pesticides within the town's borders. The ordinance at issue in *Mortier*, however, did not deal with labeling or warning issues; it required a permit for the *application* of pesticides, and imposed standards for evaluating applicants for such permits. The *Mortier* plaintiff, whose application for a permit was denied, claimed that the ordinance was preempted because FIFRA occupied the entire field of pesticide regulation.[5]

In holding that FIFRA did not preempt the entire field of pesticide regulation, the *Mortier* Court considered the language of § 136v(b) of FIFRA, quoted above. This Court recognized that § 136v(b)'s careful language concerning preemption of *labeling* would be "pure surplusage" if, as plaintiff argued, FIFRA occupied the *entire field* of pesticide regulation. *Mortier*, 501 U.S. at 614. The Court concluded:

> Whatever else FIFRA may supplant, it does not occupy the field of pesticide regulation in general or the area of local use permitting in particular.

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[5] Petitioner announces that "*Mortier* is significant because it means this court has already specifically held field preemption cannot be inferred from FIFRA." (Petition at 12). On the contrary, *field* preemption has no bearing on this case. Neither Elf Atochem, the Nebraska Supreme Court, nor any of the legion of other courts concluding that FIFRA preempts labeling claims has relied upon the doctrine of implied preemption, much less field preemption, a subcategory of implied preemption. The present case involves Congress *expressly* preempting state regulation of pesticide labeling.

Id. The Court thus used Congress' specific statement that FIFRA supplanted state pesticide *labeling* regulation as evidence that Congress did not intend FIFRA to replace *all* state pesticide regulation. The Seventh Circuit recognized this point, concluding that "[t]he Supreme Court recently noted the absolutist nature of FIFRA's pre-emption in the labeling and packaging context even as it held that FIFRA does not pre-empt generalized state regulation of pesticides." *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 370 (7th Cir. 1993) (citing *Mortier*).

Likewise, Petitioner's reliance on *Medtronic, Inc. v. Lohr*, ___ U.S. ___, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996) is misplaced. As courts interpreting FIFRA since *Medtronic* have concluded, FIFRA's preemption of labeling claims much more similar to the preemption this Court found in *Cipollone* than the preemption it rejected in *Medtronic*. As a result, courts since *Medtronic* have uniformly continued to find *Cipollone* controlling and have correctly continued to uphold FIFRA preemption of state common-law labeling claims.

The conspicuous difference between FIFRA preemption and the preemption rejected by the *Medtronic* Court is in the level of scrutiny demanded by the respective statutory schemes of the subject product. In *Medtronic*, a case interpreting the Medical Device Amendments ("MDA"), the Court relied heavily on the fact that the Food and Drug Administration ("FDA"), the agency charged with applying the MDA, barely reviewed the pacemaker at issue, and that the FDA did not even consider the safety of the device. *Medtronic*, 116 S. Ct. at 2254.

This Court recognized that the MDA's § 510k "substantially equivalent" approval process "requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly." *Id.* at 2247 (citation omitted). The *Medtronic* plurality opinion suggested that in the event of a more thorough agency review, a different result would obtain:

> The generality of [federal labeling and manufacturing] requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.

Id. at 2258.

Such a review – in which the responsible agency "weighed the competing interests" and "reached an unambiguous conclusion about how those competing considerations should be resolved" – is exactly what occurred here. In striking contrast to the FDA's cursory § 510k review, FIFRA requires EPA to thoroughly examine each pesticide and its label, and to specifically consider safety and warning issues, before allowing the pesticide to be registered and marketed. In light of this requirement, Petitioner here does not dispute that the EPA carefully considered the safety of Penncap-M and the adequacy of the safety-related warnings on its label before approving them for the market. As a consequence, the *Medtronic* Court's concern with the cursory nature of

the MDA's § 510k approval process simply has no application here. Consistent with this analysis, all 13 courts that have considered this issue since *Medtronic* have continued the pre-*Medtronic* line of cases and have held that FIFRA preempts labeling-based state common law claims.[6]

Also unavailing is Petitioner's citation to the EPA's Pesticide Regulation Notice 96-4 ("PR Notice 96-4"). Even assuming the dubious proposition that such a notice could somehow alter the statute's clear mandate of preemption, PR Notice 96-4 is entirely consistent with preemption in this case. Indeed, PR Notice 96-4 provides that "the primary focus in [FIFRA's] label approval process for agricultural pesticides involves assessing and regulating the potential risks to humans and the environment posed by such pesticides." (Petition at 5a, p. 6). Petitioner's claims against Elf Atochem rest upon his allegation that

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[6] *See Grenier v. Vermont Log Bldgs., Inc.*, 96 F.3d 559, 562-63 (1st Cir. 1996); *Hawkins v. Leslie's Poolmart*, 965 F. Supp. 566 (D.N.J. 1997); *Deshotel v. Rhone-Poulenc, Inc.*, 1997 WL 400780 (W.D. La. March 31, 1997); *Koch v. Shell Oil Co.*, 173 F.R.D. 288 (D. Kan. 1997); *Kuiper v. American Cyanamid Co.*, 960 F. Supp. 1378 (E.D. Wis. Feb. 24, 1997); *Cuevas v. E.I. DuPont de Nemours & Co.*, 956 F. Supp. 1306 (S.D. Miss. 1997); *DeAngelis v. E.I. duPont de Nemours & Co.*, 1996 WL 510092 (E.D. Pa. Sept. 5, 1996); *Didier v. Drexel Chem. Co.*, 938 P.2d 364 (Wash. Ct. App. 1997); *People v. Cotter & Co.*, 53 Cal. App. 4th 1373, 62 Cal. Rptr. 2d 368 (Cal. Ct. App. 1997); *Barnes v. Sandoz Crop Protection Corp.*, 938 P.2d 95 (Ariz. App. Div. 1997), *review granted* (Ariz. June 24, 1997); *Lewis v. American Cyanamid Co.*, 682 A.2d 724 (N.J. App. Div. 1996), *certif. granted* (N.J. July 11, 1997); *Buddington v. Sterling Winthrop, Inc.*, 1996 WL 532484, 1996 Conn. Super. LEXIS 2402 (Conn. Super. Ct. Sept. 10, 1996); *Mann v. H.W. Andersen Prods., Inc.*, 231 A.D. 500, 647 N.Y.S.2d 101 (N.Y. App. Div. 1996).

the label of Penncap-M was inadequate to protect human health. As PR Notice 96-4 recognizes, however, the EPA has already considered the safety of Penncap-M to humans and specifically approved the Penncap-M label as containing warnings adequate to protect human health.[7]

Petitioner's attempt to generate an issue for this Court through its invocation of *Chemical Specialties Manufacturers Ass'n v. Allenby*, 958 F.2d 941 (9th Cir.), *cert. denied*, 506 U.S. 825 (1992) also misfires. *Allenby* was not a tort case at all; it involved a facial challenge to California's Proposition 65, which required that pesticide sellers (among others) provide "warnings" concerning their products through any of several methods, including labeling, point-of-sale information, mailings, media notices, "and the like." *Id.* at 944. Because the challenge was to the proposition *on its face*, the plaintiff needed to demonstrate that "no set of circumstances exists under which the [proposition] would be valid." *Id.* at 943 (quoting *United States v. Salerno*, 481 U.S. 739, 745 (1987)).

The Ninth Circuit held that, because the proposition allowed compliance through means that would have no effect on the labels required by FIFRA, FIFRA therefore did not preempt that statutory warning requirement. 958 F.2d at 944-48. The Ninth Circuit noted that "there would be no need for companies to change their labels to comply with Proposition 65, *unlike the need to change labels in order to avoid state tort liability*. *Id.* at 948 (emphasis

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[7] Moreover, Petitioner never raised this issue until the Petition. Therefore, Petitioner's argument is not properly before this Court.

added). Thus, the court specifically distinguished between a statute such as Proposition 65, under which a manufacturer could comply without altering its label, and a tort suit such as Petitioner's, in which it could not.

Although the *Allenby* court did not need to reach the issue, it nevertheless recognized the argument for pre-emption of such common-law label-based tort actions as a "strong" one:

> Since FIFRA expressly preempts additional state labeling requirements, the tort suits could circumvent the preemption clause by effectively requiring additional labeling to avoid tort liability even though the states do not expressly require the additional labeling.

Id. When the Ninth Circuit *did* reach the issue in 1995, the court very clearly distinguished *Allenby* and held that FIFRA preempts *all* state tort labeling actions. *Taylor AG*, 54 F.3d at 561 n.2.[8]

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[8] Petitioner cites two older decisions for the proposition that FIFRA's preemption clause does not mean what it says when someone other than the purchaser or user alleges injury. (Petition at 16-18, citing *Macrie v. SDS Biotech Corp.*, 630 A.2d 805 (N.J. Super. Ct. App. Div.), *certif. denied*, 636 A.2d 522 (1993) and *Burke v. Dow Chem. Co.*, 797 F. Supp. 1128 (E.D.N.Y. 1992)). As indicated above, however, § 136v(b) expressly preempts states from imposing "*any* requirements for labeling" in addition to or different from the EPA's. 7 U.S.C. § 136v(b) (emphasis added). Petitioner's argument would require the manufacturer to provide additional warnings totally outside the scope of the warnings reviewed and approved by EPA.

Furthermore, requiring additional non-label warnings would undermine the very reason for establishing the EPA's uniform labeling review and approval process. Other courts

In sum, this Court decided the issue raised in this case in *Cipollone*, a fact recognized by the scores of state and federal courts that have applied the *Cipollone* holding and have uniformly found FIFRA preemption. There is simply no reason for the Court to hear this case.

CONCLUSION

For the reasons discussed above, Respondent Elf Atochem North America, Inc. respectfully asks that this Court deny the petition for writ of certiorari.

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have rejected similar arguments that a manufacturer should be required to provide non-label warnings, concluding that such claims necessarily challenge the adequacy of EPA-approved warnings. As the Eleventh Circuit stated, "any claims that point-of-sale signs, consumer notices, or other informational materials failed adequately to warn the plaintiff necessarily challenge the adequacy of the warnings provided on the product's labeling or packaging." *Papas II*, 985 F.2d at 519. Since Petitioner does not contest that Elf Atochem placed EPA-approved warnings and instructions on its Penncap-M label and packaging, "its duty to warn is satisfied, and the adequate warning issue ends." *Id.*

IN THE DISTRICT OF VALLEY COUNTY, NEBRASKA

GARY E. ACKLES, Plaintiff, vs. PENNWALT CORPORATION n/k/a ELF ATOCHEM NORTH AMERICAN, INC., A Foreign Corporation, Defendant.	)	DOC. 21 PAGE 277 CASE NO. 6277 SEVENTH AMENDED PETITION AT LAW

Plaintiff states:

INTRODUCTORY ALLEGATIONS

1. That plaintiff is a resident of Ord, Valley, County, Nebraska.

2. That defendant Pennwalt Corporation, now known as Elf Atochem North American, Inc., is a corporation organized in a state other than Nebraska with its principal place of business in Pennsylvania.

3. That on August 2, 1991, between 10:45 a.m. and 11:00 a.m., while plaintiff was delivering mail in Valley County, Nebraska, he became exposed to a pesticide identified as Penncap-M, which pesticide was being sprayed on corn in a field adjacent to the road where plaintiff was delivering the mail.

4. Said pesticide was manufactured, marketed and sold by defendant.

5. That upon information and belief, plaintiff states that the field being sprayed was located within the following legal description:

> The Northeast one-quarter (NE 1/4) of Section 21, Township 18 North, Range 14 West, the 6th PM, in Valley County, Nebraska.

6. That on August 2, 1991, Brady Coen was the pilot and applicator who was spraying the pesticide described above on the field described above.

7. That as plaintiff was driving his car with the window down, the fumes from the pesticide known as Penncap-M were ingested by plaintiff, and upon plaintiff ingesting these fumes he became nauseated and ill.

8. That on August 4, 1991, plaintiff was admitted to Good Samaritan Hospital in Kearney, Nebraska with an admission diagnosis of "exposure to organophophate poisoning" and was eventually discharged on August 11, 1991.

9. That as a direct and proximate result of the negligence and breach of warranty by the defendant, as more fully described below, the plaintiff sustained damages, as more fully described in paragraph 19 below.

FIRST THEORY OF RECOVERY

NEGLIGENCE

Plaintiff realleges Paragraphs 1 through 9, as if fully set forth herein.

10. That the defendant had a duty to exercise reasonable care and caution concerning the design, production, manufacture and distribution of the pesticide which is the subject matter of this Petition.

11. That the defendant violated its duties to the plaintiff and others similarly situated, in one or more of the following particulars:

a) In negligently designing, producing, manufacturing, distributing and selling this product so that as a proximate result thereof plaintiff was injured;

b) In negligently failing to conduct sufficient, reasonable and adequate comprehensive research concerning the product;

c) In negligently failing to make adequate and sufficient testing of this product;

d) In negligently failing to adequately and properly inspect this product;

e) In negligently designing, producing, manufacturing, distributing and selling this product without making adequate safety provisions or carrying out safety measure relating to this product;

f) In negligently designing, manufacturing and selling this product which was inherently dangerous when produced and sold, and likely to inflict unreasonable risk of harm;

g) In negligently failing to perform its continuing non-delegable duties with respect to this product to withdraw it from the market for use due to lack of safety.

12. As a direct and proximate result of the defendant's negligence, as set forth above, plaintiff has sustained damages as set forth in Paragraph 19 below.

SECOND THEORY OF RECOVERY

BREACH OF IMPLIED WARRANTIES

Plaintiff realleges Paragraphs 1 through 12 as if fully set forth herein.

13. That the defendant impliedly warranted that the pesticide sprayed would be fit for the purpose intended.

14. That the defendant impliedly warranted that the pesticide would be free from defects creating an unreasonable risk of harm.

15. That the defendant impliedly warranted that the pesticide would be manufactured and distributed consistent with good safety practices, including adequate safety precautions, and be of merchantable quality.

16. That the pesticide, which is the subject matter of this action, was not of merchantable quality, nor was it fit, safe or in proper condition for the use in which it was designed to be used.

17. That the defendant breached one or [sic] of the aforesaid warranties.

18. That the breach of the defendant's implied warranties was a proximate cause of plaintiff's injuries.

19. Plaintiff has sustained the following by way of damages:

a) Organophosphate poisoning;

b) Depression and anxiety;

c) Physical pain and mental suffering in the past and it is reasonably certain that plaintiff will incur physical pain and mental suffering in the future;

d) Medical bills in the past and it is reasonably certain that plaintiff will sustain medical bills in the future;

e) Loss of wages in the past and it is reasonably certain that plaintiff will sustain future loss of wages; and,

f) Permanent impairment of plaintiff's earning capacity;

g) Permanent injury; and

h) Permanent disability.

20. Plaintiff was 52 years of age at the time of this incident and had a life expectancy of 23.3 years.

21. Plaintiff's wife, Jeanne Ackles, has assigned to plaintiff in writing all causes of action she may have as a result of this accident. A copy of said Assignment is attached hereto, marked Exhibit "A" and incorporated herein by reference.

WHEREFORE, plaintiff prays for judgment on his First and Second Theories of Recovery against defendant for his special damages, general damages as allowed by law, interest and costs.

DATED this 23rd day of July, 1997.

GARY E. ACKLES, Plaintiff

By: /s/ J. Marvin Weems #14428
P.O. Box 170
Ord, Nebraska 68862
(308) 728-3285

and E. Terry Sibbernsen #13826
Mandy L. Stringenz #20208
E. TERRY SIBBERNSEN, P.C.
8805 Indian Hills Drive, #325
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing pleading was mailed by regular U.S. mail to Brian Nolan, 300 S. 19th St. #302, Omaha, Nebraska 68102, on the 23rd day of July, 1997.

/s/

EXHIBIT "A"

ASSIGNMENT

KNOW ALL MEN BY THESE PRESENTS, that I, Jeanne Ackles, of Ord, Valley County, Nebraska, in consideration of the sum of One and No/100 Dollars ($1.00) and other good, valuable and sufficient consideration to me paid, the receipt whereof is hereby confessed and acknowledged, do hereby sell, assign, transfer, deliver and set over unto Gary E. Ackles, his executors, administrators and assigns, and to him and their own proper use

and benefit, any and all sums of money due and owing to us, and all claims demands and cause or causes of action of any kind whatsoever which we have had or now have or may have against Dick Luttrell and Pletcher Flying Service, Inc., a corporation, by reason of the medical, hospital and other expenses which I have incurred by reason of injuries sustained by my husband Gary E. Ackles as a result of an accident which occurred on August 2, 1991, in Ord, Valley County, Nebraska.

I hereby constitute and appoint Gary E. Ackles, his executors, administrators and assigns, my true and lawful attorney with full power of substitution and revocation for me in my own name, but for the sole use and benefit of Gary E. Ackles, his executors, administrators and assigns, to ask, collect, demand and use for, in his own name and right, and to receive, compound and give acquittances for the claim or claims of any party thereof.

WITNESS my hand this 8th day of February, 1993.

/s/
JEANNE ACKLES